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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability
Litigation

No. MD-15-02641-PHX-DGC

LISA HYDE and MARK HYDE, a married
couple,

Plaintiffs,

v.

C.R. BARD, INC., a New Jersey corporation
and BARD PERIPHERAL VASCULAR, an
Arizona corporation,

Defendants.

**PLAINTIFFS' RESPONSE TO
DEFENDENTS' MOTION *IN LIMINE*
NO. 3 TO EXCLUDE EVIDENCE OF
THE SIMON NITINOL FILTER AS A
REASONABLE ALTERNATIVE
DESIGN**

(Assigned to the Honorable David G.
Campbell)

(Oral Argument Requested)

ARGUMENT AND CITATION OF AUTHORITY

I. The Issue Of Reasonable Alternative Design Is For The Trier Of Fact.

The Court's Order on Defendants' Motion for Summary Judgement states "[p]laintiffs have presented sufficient evidence of a reasonable alternative design to survive summary judgment" related to evidence of caudal anchors and penetration limiters. (Doc. 12007). In footnote 5 to the above, the Court addressed the dispute regarding the Simon Nitinol Filter (here after "SNF") as an alternative design for Plaintiffs' design defect claim; "given the ruling above, the Court need not resolve this issue for purposes of summary judgement." *Id.*

1 A motion *in limine* should not be used to resolve factual disputes or weigh evidence.”
 2 *Research Corp. Techs., Inc. v. Microsoft Corp.*, CV-01-658TUCRCJ, 2009 WL 2971755, at
 3 *1 (D. Ariz. Aug. 19, 2009)(citing *C & E Servs., Inc. v. Ashland, Inc.*, 539 F.Supp.2d 316, 323
 4 (D.D.C.2008). Defendants offer no basis for excluding argument that the SNF is a reasonable
 5 alternative design.¹ Defendants attempt to use a motion *in limine* to address a factual issue for
 6 the jury; whether Plaintiffs can establish the SNF would have “reduced” or “avoided” the harm
 7 posed to Mrs. Hyde. Wis. Stat. 895.047(1)(a).

8 **II. The G2X Or Eclipse Filters Were Cleared As Permanent Devices With An** 9 **Option To Retrieve By The FDA.**

10 Because the SNF is a permanent filter does not make it less of a reasonable alternative
 11 design for the G2X or Eclipse filter. Both were submitted for clearance to the FDA as
 12 *permanent* devices with an option to retrieve.² Each of Bard’s IVC filters is predicated on the
 13 one before it, that is Eclipse is predicated on G2X, G2X on G2, G2 on Recovery, and Recovery
 14 on SNF. Defendants’ argue the SNF filter cannot be a reasonable alternative design because
 15 the filter cannot be retrieved; this argument fails as Defendants cannot have it both ways,
 16 purport to the FDA the predicate devices are substantially equivalent and then argue to the
 17 Court the predicate devices are unrelated. Bard’s Medical Director, Dr. David Ciavarella, even
 18 acknowledged that both the G2 and SNF are permanent filters, “The G2 is a permanent filter,
 19 we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn’t
 20 doctors be using that one rather than the G2?” Ex. C, BPVE-01-00245186. The 2008 Patient
 21 Brochure for the G2 device states in response to the question “how long will the filter last?”
 22 that the “G2 Filter is designed to be a permanent implant and not to be removed, repositioned
 23

24 ¹ Several Circuit Courts prohibit the use of motions *in limine* to convert into summary judgment
 25 motions; a motion *in limine* should focus on narrowing evidentiary issues for trial or precluding
 26 unnecessary trial interruptions and not resolving a legal matter which is cast as an evidentiary issue.
 27 See *Louzon v. Ford Motor Co.*, 718 F.3d 556, 561 (6th Cir. 2013)(citing *Meyer Intellectual Props.*
 28 *Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1378 (Fed.Cir. 2012); *Bradley v. Pittsburgh Bd. of Educ.*, 913
 F.2d 1064, 1070 (3d Cir. 1990)(internal quotation marks omitted); *Mid-America Tablewares, Inc. v.*
Mogi Trading Co., 100 F.3d 1353, 1363 (7th Cir.1996).

² Ex. A, G2X 510(k) application (K080668), BPV-17-01-00130498 at 663; Ex. B, Eclipse 510(k)
 application (K093659), BPV-17-01-00116991 at 996.

1 or replaced.”³ Ex. D, BPV-17-01-00137624 at 629; Ex. E, BPV-17-01-00142912. Further,
 2 testimony from Bard’s Product Manager, Rob Carr, provides evidence the G2 and G2X filters
 3 were permanent devices, Ex. F, Carr Dep. Tr., 11/5/2013, 41:11-41:24:

4 Q. And during this time frame – that is the Recovery era, the G2 era and the G2 Express
 5 era – did Bard have a truly permanent filter that was commercially available?

6 A. **All of them are truly permanent.**

7 To distinguish the SNF design from the filter implanted in Mrs. Hyde, Defendants
 8 point to Plaintiff’s implanting physician, Dr. Henry. Dr. Henry may have chosen a filter with
 9 a retrievable option, but he also understood Mrs. Hyde’s filter “could be permanent or
 10 temporary.”⁴ Also, Mrs. Hyde testified her doctors said nothing about retrieving the filter,
 11 “[w]hat I remember was he said these are temporary filters but we’re leaving them in. We leave
 12 them in, and it’s okay.”⁵ Mrs. Hyde’s filter was approved as a permanent device and
 13 understood to have the potential to be used as a permanent device by her implanting physician.
 14 The filter’s potential to be retrievable does not nullify the argument that the SNF was a
 15 reasonable alternative design. More importantly, the August 29, 2005 EVEREST Medical
 16 Monitoring Meeting Minutes reveal at 6 months the G2 filter “must be considered
 17 permanent.”⁶ Dr. Kris Kandarpa, the medical monitor of the EVEREST retrievability trial
 18 confirmed Bard chose not to conduct a long-term study to determine risks as a permanent
 19 device; the EVEREST protocol called for retrieval within 6 months of initial implantation. Ex.
 20 I at 196:23-197:1.

21 Defendants cite one Wisconsin case to argue that a reasonable alternative design must
 22 not “make the product something else.” *See Godoy ex rel. Gramling v. E.I. du Pont de Nemours*
 23 *& Co.*, 743 N.W.2d 159, 162 (2007).⁷ The retrieval option of the G2/G2X /Eclipse filter is not

23 ³ G2X is identical in design to the G2 with a snare at the filter top. G2X is identical in design to the
 24 Eclipse with the addition of an electropolished finish. *See*, Ex. A to Doc. 5398, Declaration of Robert
 Carr at ¶¶47, 103,105, 114, 119, and 120.

25 ⁴ Ex. G, Henry Dep. Tr. at 72:23-73:1.

26 ⁵ Ex. H, Hyde Dep. Tr., 1/25/17, at 75:14-76:1; 81:13-18; 83:6-10.

27 ⁶ Ex. I, Kandarpa Dep. Tr., 7/19/18, at 73:3-22, Ex. J, BPVEFILTER-25-00097877.

28 ⁷ Defendants cite to several cases outside the jurisdiction to support “a different product is not a safer
 alternative design”, without explanation or discussion of how the cases apply to Wisconsin law and
 the facts here. Section II of this motion and ¶¶ 1-6, 113-128, 150-190 to Plaintiffs’ OSOF establish
 the SNF, G2X, and Eclipse filters are all permanent devices with options for retrieval. (Doc. 8186).

1 an ingredient, like in *Godoy*, that makes the product “something else.”⁸ These devices can be
 2 considered as much a permanent device as an optional device; in fact, its similarity to its
 3 permanent predecessors is the very reason Bard was able to use the 510(k) application process
 4 to seek clearance of its products instead of the more rigorous Premarket Approval safety
 5 review process. If the device can be used both permanently and temporarily, it cannot be
 6 logically argued that one or the other is an ingredient that “makes the product something else.”

7 **III. Plaintiffs’ Offer Sufficient Evidence Supporting SNF Filter Would Have 8 Reduced The Harm Posed By The G2X/Eclipse Filter.**

9 A manufacturer may be liable under Wisconsin Statute §895.047(1)(a) where the
 10 alternative design would have “reduced” or “avoided” the harm posed by the product.
 11 Plaintiffs incorporate by reference paragraphs 1-6, 113-128, 150-190 to Plaintiffs’ Omnibus
 12 Statement of Facts in Support of Their Response to Defendants’ Motion for Summary
 13 Judgement to establish evidence that the SNF would have reduced or avoided harm posed by
 14 the G2X/Eclipse to Mrs. Hyde. *See*, Doc. 8186; *See also*, Wis. Stat. 895.047(1)(a). Further,
 15 Plaintiffs’ expert Dr. McMeeking offered a 12-page opinion concluding “from my engineering
 16 perspective the design of the SNF is substantially better than those of the Recovery, G2 and
 17 similar Bard filters, with respect to migration, tilt, arm fracture and arm perforation, after
 18 considering the combination of attributes that are positive or negative in each case for each
 19 filter design. Therefore, based on my assessments it is my opinion that, in sum, the SNF is a
 20 safer filter than the Recovery, G2 and similar Bard filters.” Ex. K, Rebuttal Report of Robert
 21 McMeeking, dated 05/11/17.

22 **IV. Conclusion.**

23 Plaintiffs request this Court deny Defendants Motion *in Limine* No. 3.
 24
 25

26 Further, Defendants misstate Dr. McMeeking; he testified he is not offering an opinion about the use
 27 of permanent and retrievable filters because he is not a medical doctor. *See*, Def. Mot., Ex. B.

28 ⁸ *Godoy* involved a product known as white lead carbonate pigment. The alleged design defect was
 the presence of lead; court found “without lead there can be no white lead carbonate” and “the
 presence of lead “is a characteristic of the product itself” so it was not a design feature that made it
 defective. *Id.* at 678. The facts in *Godoy* are inapposite to the design features in the present filter.

1 RESPECTFULLY SUBMITTED this 28th day of August 2018.

2
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4 By: /s/ Mark S. O'Connor

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14 **CERTIFICATE OF SERVICE**

15 I hereby certify that on this 28th day of August 2018, I electronically transmitted the
16 attached document to the Clerk's Office using the CM/ECF System for filing and
17 transmittal of a Notice of Electronic Filing.

18 /s/ Jessica Gallentine